

**APPLICATION FOR
UNITED STATES PATENT
IN THE NAME OF**

DAN KALAS , L. MICHAEL CUTRER, AND JACK WEBB

ASSIGNED TO

NORTH AMERICAN SCIENTIFIC, INC.

FOR

THIN RADIATION SOURCE AND METHOD OF MAKING THE SAME

DOCKET NO. 81206-243306

**PREPARED BY:
PILLSBURY WINTHROP LLP
725 S. FIGUEROA STREET, SUITE 2800
LOS ANGELES, CA 90017-5406
(213) 488-7100**

EXPRESS MAIL NO. EL 724 025 964 US

09880190-061201

THIN RADIATION SOURCE AND METHOD OF MAKING THE SAME**BACKGROUND**

5 Nuclear imaging equipment, e.g., medical equipment such as gamma cameras, must be regularly calibrated to ensure that images produced thereby accurately reflect the subject being imaged. Generally, this calibration is performed using a radiation source of known uniformity as a reference. These sources are also known as sheet sources or flood sources. These nuclear imaging devices generally detect the emission of radiation, such as gamma rays, from a source. In medical applications, the source may be, for example, an implanted brachytherapy seed, a catheter, a biopsy needle, or an ingested or injected radionuclide solution. The devices may include a collimator for channeling emitted radiation to a detector (e.g., a scintillation crystal), which produces a signal based on the direction, location and intensity of the emitted radiation. By collecting and analyzing these signals, an accurate representation of the spatial distribution, location and intensity of the radiation source can be achieved.

10
15
20 Regular calibration of the nuclear imaging equipment helps to ensure that detector signals are accurately converted into a representation of the source. Errors in imaging can result from misalignment, software failure, or electronic failure of parts within the imaging equipment. When the nuclear imaging camera images a known uniform radiation source, such as a flood source, these equipment failures will appear as non-uniformities in the image of the known uniform source. These non-uniformities can be corrected by proper tuning or calibration of the gamma camera or can be accounted for in the capturing of subsequent non-uniform images.

Accordingly, it is important that radiation sources used for calibration have a relatively uniform or, at least, well-known distribution of activity, both in terms of intensity and spatial distribution. Moreover, because such sources must be frequently handled by personnel, it is

important that these sources be sufficiently light and durable and that the radiation exposure of handling personnel be minimized.

Current flood sources are generally made of cast epoxy in which a radioisotope is uniformly distributed and sealed within an outer housing of plastic or metal. Such sources are generally bulky and heavy and are difficult and messy to manufacture. Large molds or leveling tables are required to form the epoxy to the desired shape. Moreover, because radiation is involved, a messy manufacturing process that produces significant amounts of radioactive waste residue is unnecessarily expensive.

After a while, radiation sources used for calibration become depleted. When the sources become depleted they are generally returned to the manufacturer for disposal and replacement with a fresh source. Disposal of a partially depleted source creates additional radioactive waste, which is costly to dispose. Moreover, the sources are bulky and are often shipped in shielded containers that are also large and heavy, resulting in high shipment costs in addition to waste disposal costs.

For these reasons, it is desirable to create a radiation source that is lightweight and/or flexible, that minimizes the mass of radioactive waste when replacement is necessary, and that is simple and clean to manufacture.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts a flood source embodiment of the present invention;

FIGURE 2 illustrates a system that may be used to make radiation sources according to embodiments of the present invention.

09360190-061301
"061301"
"061301"

DETAILED DESCRIPTION

The present invention relates to radiation sources that may be used, for example, in the calibration of nuclear imaging equipment, such as gamma or other nuclear measuring systems such as SPECT or PET cameras. The present invention is also directed to methods of making and using such radiation sources. Embodiments of the present invention are directed to a radiation source that contains a substrate upon which a radioactive deposit has been deposited. The radioactive deposit may be deposited as a solution and affixed to the surface of the substrate to prevent movement of the radioactive deposit during use of the radiation source. In embodiments of the invention, the substrate may be flexible, so that the form factor of the substrate may be reduced (e.g., by manipulating the shape of the substrate, such as by folding or rolling) for shipment in a smaller shielded container. In embodiments of the source of the present invention, the outer housing containing the substrate may be opened so that a depleted substrate may be replenished or an additional compensatory substrate may be inserted.

Embodiments of the method of making sources according to the present invention may involve forming a radioisotope-containing solution that can be deposited on the surface of the substrate in a selected radioactive deposit. The radioisotope-containing solution may include a radioisotope (or some form thereof) and a solvent. In embodiments of the invention, the solution may also contain a binding agent to affix the radioisotope to the surface of the substrate. In embodiment of the invention, the solution may be deposited on the surface of the substrate using a inkjet-type printhead.

FIG. 1 illustrates a circular flood source according to an embodiment of the present invention. The source is enclosed in an outer housing 1, a portion of which is shown as removed to reveal the inner substrate 2 and radioactive deposit 3 contained therein. The outer housing 1 may be relatively thin and made of a radiotranslucent material, such as aluminum or plastic.

This allows radiation emitted from the substrate 2 to pass through the outer housing 1 for imaging by an imaging device. In embodiments of the invention, the outer housing 1 may be sufficiently rigid to allow fixed mounting of the source during calibration procedures.

The outer housing 1 may contain a substrate 2 having a "front" surface upon which the radioactive deposit 3 may be deposited to achieve a desired activity pattern. In embodiments of the invention, the substrate 2 may be fixed in place in the outer housing 1 by an adhesive, pins, clips, or some other attachment feature, while in other embodiments, the substrate 2 may be fixed in place within the outer housing 1 by the size and/or shape of the outer housing 1 relative to the substrate 2. In some flood source embodiments, the activity pattern may be uniform across the entire surface of the substrate. In other embodiments, the radioactive deposit 3 may be drawn to mimic an implanted radiation emitter (e.g., a brachytherapy seed) or may be drawn to match a specified pattern of spatial distribution and/or activity level (intensity).

In particular embodiments of the invention, the substrate 2 may be a flexible sheet of paper, plastic or some other material. The substrate 2 material may be selected based upon its ability to retain the radioactive deposit 3 in a fixed form. The substrate 2 may be radiopaque, such that radiation is emitted from only the surface of the substrate 2 upon which the radioactive deposit 3 is deposited. The radioactive deposit 3 imprinted on the substrate 2 may include a radioisotope with a relatively long half-life, such as Cobalt-57 or Gold-153.

Although the radioactive deposit 3 is described as being deposited on a "surface" of the substrate 2, it should be noted that this surface need not be exposed. For example, the surface of the substrate 2 upon which the radioactive deposit 3 is deposited may be covered with a sealing layer, such as a layer of plastic or polymer. The sealing layer may be radiotranslucent and may be applied by heating (e.g., lamination), immersion (e.g., in a bath), painting, spraying or a

similar suitable process. A sealing layer may be deposited to affix the radioactive deposit to the surface of the substrate **2** and/or to prevent damage to, or removal of, the radioactive deposit **3** or substrate **2**.

In an embodiment of the invention, the radioactive deposit **3** may be deposited on the surface of the substrate **2** in the form of a solution (the "deposited solution"). The deposited solution may contain dissolved radioisotope, a solvent and a binding agent. The solvent may be an inorganic solvent (e.g., water) or an organic solvent, (e.g., isopropyl or other alcohols, oils, ketones, esters, or glycols), and the solution may be created by dissolving a salt or other compound formed from the radioisotope in the solvent. In an alternative embodiment, the radioisotope may be adsorbed or chemisorbed to a particulate carrier that is evenly dispersed throughout the solution. In alternative embodiments of the invention, the deposited solution may contain a radioisotope precursor that is rendered a radioisotope by neutron bombardment after deposition on the substrate **2**. The solvent may evaporate after the deposited solution has been deposited on the surface of the substrate **2**, leaving the radioisotope and the remaining ingredients in the deposited solution to form the radioactive deposit **3**.

In embodiments of the invention, the deposited solution may also contain a binding agent, such as an organic resin (e.g., acrylics, styrenes, polyesters, polyamides, polyvinyl acetate copolymers, polyketones, phenolics, polyvinylbutyrals, polyvinylpyrrolidones, and maleic anhydride copolymers) or an inorganic binding agent (e.g., sodium silicate). Such binding agents may be used to affix the radioactive deposit **3** to the surface of the substrate **2** and may be chosen based on the characteristics of the substrate **2** and the characteristics of other elements in the deposited solution. For example, the binding agent may be chosen based upon the effects of

a radioisotope's activity on its ability to bind to the surface of the substrate 2 or its viscosity during the deposition process.

In further embodiments of the invention, the deposited solution may include a colorant, such as, a dye or pigment. The color of the colorant may correspond to the radioisotope or radioisotope precursor in the deposited solution. Moreover, as described in greater detail with respect to FIG. 2, in the radioactive deposit 3 as deposited, the colorant may serve as a visual indicator of the activity level of various portions of the radioactive deposit 3 or of the radioactive deposit 3 as a whole. In such embodiments, the accuracy of the deposition process in creating a uniform or specified radioactive deposit 3 may be visually verified during the manufacturing process by inspecting the color pattern created by the colorant.

The outer housing 1 may include a border 4. The border 4 may be radiopaque so as to minimize radiation emitted into the hands of personnel maneuvering the source during calibration procedures without substantially changing the radioactive deposit of the source as seen by the imaging device. Although not shown in the pictured embodiment, the border may include handles or other features that make handling of the source by personnel more convenient. Furthermore, the back surface of the outer housing 1 or the substrate 2 may be radiopaque to further minimize radiation exposure to handling personnel.

FIG. 2 illustrates a system that may be used to deposit the radioactive deposit 3 on the surface of the substrate 2 according to an embodiment of the present invention. The blank substrate 2 may be passed in front of a liquid deposition head 101. In embodiments of the invention, the liquid deposition head 101 may be an inkjet-type printhead as can commonly be found in the InkJet or DesignJet lines of inkjet printers available from Hewlett-Packard Company of Palo Alto, California or the Stylus line of inkjet printers available from Seiko Epson

Corporation of Japan. In particular embodiments, a large-format inkjet-type printer may be used to accommodate a large substrate 2.

The blank substrate 2 may be positioned relative to the liquid deposition head so that the deposited solution may be placed on different portions of the front surface of the substrate 2. In the embodiment shown in FIG. 2, this may be achieved by rotating rollers 102a and 102b and 103a and 103b so as to move the substrate 2 while the position of the liquid deposition head 101 remains fixed. One or more of the rollers 102a and 102b and 103a and 103b may be driven by a motor. In the embodiment shown in FIG. 2, the rollers 102a and 102b and 103a and 103b are paired as pinch rollers. Such an embodiment may be particularly suitable where the substrate 2 is in the form of a cut sheet.

In alternative embodiments, different roller configurations may be used to move the substrate 2. For example, in embodiments of the invention in which the substrate 2 is a continuous web, unpaired rollers may be used and one surface of the substrate 2 (e.g., the back surface) may be held in tension against the surface of the rollers. The continuous web of substrate 2 may be cut into individual sheets of substrate 2 after the radioactive deposit 3 has been deposited on the front surface.

In other embodiments of the invention, the substrate 2 may be moved using different feeding mechanisms, such as a vacuum belt, air bearing or the like. These feeding mechanisms may be chosen to minimize contact with the front surface of the substrate before the radioactive deposit 3 has been affixed thereon. Alternatively, the liquid deposition head 101 may be moved relative to a fixed-position substrate. In such an embodiment, the liquid deposition head 101 may be mounted on a carriage and the carriage may be moved in the x-, y- and/or z-axes using drive screws.

As generally described above, the radioactive deposit **3** may be created by placing the deposited solution **104** on the front surface of the substrate **2**. A controller **106** may communicate with the liquid deposition head **101** to control the placement of the deposited solution **104** on the front surface of the substrate **2**. Control signals from the controller **106** to the liquid deposition head **101** may control the rate at which the deposited solution **104** is released from the liquid deposition head **101**. Moreover, in embodiments in which the liquid deposition head **101** includes multiple openings, nozzles or jets (hereinafter commonly referred to as "openings") through which the deposited solution **104** may be released, the control signals from the controller **106** may be used to selectively open and close or activate and deactivate these openings.

The deposited solution **104** may be stored in a container **105** and fed to the liquid deposition head **101** through a feed source **108** and a feed line **107** (or multiple feed lines in embodiments in which the liquid deposition head **101** has multiple openings). In embodiments of the invention, the feed source **108** may be a pump or other device suitable for causing forced flow of the deposited liquid **104**. The characteristics of the feed source may be selected based on the viscosity of the deposited liquid, the size of the feed line **108** and other factors. The feed source **108** may receive signals from the controller **106** so as to control the flow of deposited solution **104** to the liquid deposition head **101**. The received control signals may regulate the differential pressure applied by the feed source **108** to generate forced flow or may direct flow to specified feed lines in embodiments in which multiple feed lines are used. In other embodiments, the feed source **108** may be a valve and differential pressure to force flow of the deposited solution to the feed line **107** may be created by a sufficient gravity head.

In alternative embodiments, the dissolved radioisotope (i.e., radioisotope and solvent solution) may be stored in the container 105 and mix in additional ingredients of the deposited solution 104 shortly before deposition of the radioactive deposit 3. This may be desirable in embodiments in which the fluid properties of other ingredients of the deposited solution 104 (e.g., binding agent, colorant) are adversely affected by the activity of the radioisotope. In such 5 embodiments, mixing may be done within the liquid deposition head 101 or in a separate mixing tank positioned between the feed source 108 and the liquid deposition head 101.

In embodiments of the invention in which the liquid deposition head 101 is moved, the feed line 107 may be flexible and/or extendible so as to permit a suitable range of motion for the liquid deposition head 101. The size of the feed line may be selected based upon the viscosity of the deposited solution 104 so as to ensure free flow of the deposited solution 104 to the liquid deposition head 101. The connections between the feed line 107 and the feed source 108 and between the feed line 107 and the liquid deposition head may be made liquid-tight. Particularly in embodiments in which the deposited solution contains active radioisotope, liquid-tight connections may minimize the amount of active deposited solution leaking during the deposition process so as to lessen radiation exposure to manufacturing personnel and minimize radioactive waste produced during the manufacturing process.

In embodiments in which the deposited solution 104 contains active radioisotope, the container 105 may be shielded so as to minimize the radiation exposure of other components in the system. Where the deposited solution 104 contains a solvent or other ingredient that is 20 susceptible to evaporation, the container 105 may be sealed to prevent such evaporation. In particular embodiments of the invention, the container may be similar to a standard inkjet-type ink cartridge.

In embodiments of the invention, the deposition process may be done in layers, with each layer being associated with a uniform activity density and additional layers being deposited on portions of the radioactive deposit **3** corresponding to higher levels of activity. This process may resemble the hue-saturation-value process for inkjet-type printing. In fact, in embodiments in which the deposited solution **104** includes a colorant, the resulting radioactive deposit **3** may resemble grayscale or color printing carried out using a hue-saturation-value process.

Alternatively, the radioactive deposit **3** may be broken down into a number of areas ("pixels") and the number of drops of deposited solution **104** placed within a pixel of the radioactive deposit **3** may determine the activity level of the pixel. In embodiments of the invention in which each pixel is relatively small, the resulting radioactive deposit may appear consistent as a result.

In embodiments of the invention involving thermal "printing," the deposited solution **104** may be propelled out of the liquid deposition head **101** by heating a resistive element within the liquid deposition head **101** to create a bubble in the chamber filled with the deposited solution **104**. As the resistive element is heated, the bubble expands, pushing the deposited solution out of the liquid deposition head **101** toward the surface of the substrate **2**. In alternative embodiments involving vibrational "printing," deposited solution **104** may be expelled from the liquid deposition head **101** by the vibration of a transducer. The transducer may have piezo-electric properties (i.e., may expand or contract when electrical current is passed through it), and vibration may be induced by charging or removing charge from the transducer.

While the description above focuses on the use of an inkjet-type printing mechanism, a person of ordinary skill in the art will recognize that other types of printing devices may be used to place the radioactive deposit **3** on the surface of the substrate **2**. For example, a variety of

impact or non-impact printers (e.g., solid ink printers, dot matrix printers, character printers, thermal wax printers), plotters, airbrushes or the like may be used.

Returning to FIG. 1, in embodiments of the invention, the outer housing 1 may be opened so that the substrate 2 with the deposited radioisotope 3 may be removed. In such embodiments, the outer housing 1 may include a fastener. Furthermore, in such embodiments, the outer housing 1 may be hinged or otherwise constructed so that the parts of the outer housing 1 remain in contact at a point(s) when the outer housing 1 is opened. This may prevent misalignment of the parts of the outer housing 1 when the outer housing 1 is closed. The fastener may be a lock, a snap or a similar latching mechanism that may be selectively unfastened and may require a key, dial combination or other access device for opening. Alternatively, the fastener may be a screw, pin or other mechanism that must be removed for the outer housing to be opened.

In some embodiments, the outer housing may be opened by personnel using the source or other personnel at the customer's site, so that depleted substrates can be shipped back to the manufacturer for replenishment. Where the substrate 2 is flexible, the using personnel may change the shape of the substrate 2 to reduce its form factor (e.g., by manipulating the substrate by rolling it into a cylindrical shape or folding it) and the protective shipping container may be smaller in size than the expanded substrate 2. Because the shipping container must be fully-shielded and because shielding materials are generally heavy, shipping the depleted substrates 2 back to the manufacturer (and shipping replenished substrates to the customer) without the outer housing 1 and with smaller shipping containers may significantly reduce shipping expenses.

In embodiments with a outer housing 1 that may be opened, the entire source, when depleted, may be returned to the manufacturer. The manufacturer may open the outer housing 1, measure the remaining activity level of the depleted substrate 2 ("the pattern of depleted

activity") and create a second substrate with an activity level matching the difference between that of a fresh substrate and the depleted substrate 2. The manufacturer may then place the second substrate in the outer housing 1 and close the outer housing 1 before sending it back to the customer as a fresh source. In such a system, the manufacturer may note that the depleted
5 substrate 2 exhibits a pattern of depleted activity and may cause the second substrate to be imprinted with a compensatory pattern of deposited radioisotope so that the combined activity pattern of the depleted substrate 2 and the second substrate substantially matches the activity pattern of a fresh substrate. Alternatively, the compensatory pattern of deposited radioisotope may be deposited over the depleted radioactive deposit 3 on the first (depleted) substrate 1. The
10 pattern of depleted activity may be even or uneven depending, in part, upon whether the radioactive deposit 3 initially deposited on the substrate was uniform or not, whether one or more types of radioisotopes were combined to form the radioactive deposit 3, etc.

While the description above refers to particular embodiments of the present invention, it should be readily apparent to people of ordinary skill in the art that a number of modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true spirit and scope of the invention. The
15 presently disclosed embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description. All changes that come within the meaning of and range of equivalency of
20 the claims are intended to be embraced therein.